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Medical Equipment and PPE Regulatory Reference Guide

The COVID-19 pandemic has had an unprecedented impact on the world. As healthcare providers work on the front line to combat the pandemic, the supply of ventilators, face masks and other personal protective equipment (PPE) are growing scarce. As manufacturers, many of you are in the process of supporting these ongoing needs. To assist you in the fight, we've put together this guide to share the proper protocols for U.S. regulatory submission, as provided by the FDA, CDC and ASTM, to help ensure your products get to market as quickly as possible, and into the hands of our healthcare providers.

Free Resources to support COVID-19	Relevant ASTM Testing Standards & Specifications	Recent Final Medical Device Guidance Documents	FDA Emergency Use Authorizations
Guidance for Medical Gloves and Gowns	Enforcement Policy for Gowns, Gloves, etc.	FAQs of Shortages of Surgical Masks and Gowns:	Questions about Personal Protective Equipment (PPE)
FDA Industry Guidance for Face Masks & Respirators	Enforcement Policy For Face Masks and Respirators	N95 Respirators and Surgical Masks (Face Masks)	MOU using 3D Printing between NIH, FDA, and VHA
FDA Industry Guidance for Ventilators	Enforcement Policy for Ventilators	Ventilator Supply Mitigation Strategies	FDA Ventilator and EUA Guidance
U.S Customs and Border Protection	CSMS #42124872 Filing PPE & Medical Devices	**Reminder** Format the correspondence in accordance with the relevant FDA guidance document to expedite response.	

For additional FDA contact information, please call: 1-888-INFO-FDA
For questions regarding the appropriate product coding, email the FDA.
If requesting emergency use authorizations for diagnostic devices, email the FDA.
If requesting emergency use authorizations for non-diagnostic devices, email the FDA.

